

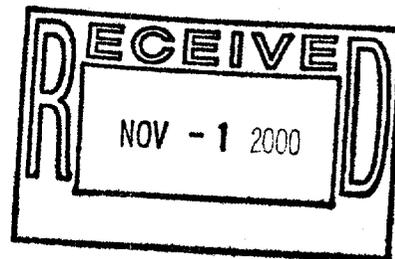
Datum 30.10.00  
Bereich/Abr. CHN-BS; Regulatory Affairs  
Zuständig Dr. Najib Sehat  
Tel. 0 61 51/72 6060  
Fax 0 61 51/ 8946  
E-mail najib.sehat@merck.de  
Ihr Schr. vom  
Ihre Zeichen

# MERCK

Merck KGaA · Darmstadt  
Deutschland

7706 '00 553 -1 A7M  
[October 30, 2000]

Office of Nutritional Products, Labeling,  
and Dietary Supplements (HFS-800)  
Center for Food Safety and Applied  
Nutrition  
Attention: Mr. John B. Foret  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204



## NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

Merck KGaA files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act. Merck KGaA is a raw materials supplier of dietary ingredients to manufacturers of dietary supplements.

Name of dietary supplement: Calcium salt of L-5-methyltetra-hydrofolate (L-5-methyl-THF)

Dietary ingredient: L-5-methyltetra-hydrofolate (L-5-methyl-THF)

### Statements

- Is essential for one carbon transfer reactions involved in protein biosynthesis and DNA/RNA methylation.
- Supports the body's normal methyl metabolism.
- Supports normal DNA synthesis.
- Plays a key role in one-carbon metabolism.
- Folates function metabolically as coenzymes that transport single carbon fragments from one compound to another in amino acid metabolism and nucleic acid synthesis.
- Efficiently corrects folate deficiency. The incidence of folate deficiency in the U.S. ranges from 2 to 14%.
- Efficiently corrects elevated homocysteine levels.
- Less likely than folic acid to mask vitamin B12 deficiency by reversing the anemia. The incidence of vitamin B12 deficiency in the total U.S. population is less than 1%.

975-0162

Kommanditgesellschaft auf Aktien  
Handelsregister AG Darmstadt HRB 6164  
Sitz der Gesellschaft, Darmstadt  
Vorsitzender des Aufsichtsrats:  
Heinrich Hornef

Geschäftsleitung und pers. haftende Gesellschafter:  
Bernhard Scheuble (Vorsitzender),  
Michael Römer (stellvertretender Vorsitzender),  
Michael Becker, Thomas Schreckenbach,  
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LET 6182

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Tel. 0 61 51/72 6060  
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- Is an essential B vitamin.
- Alcohol may deplete folate levels in the body.
- The body's preferred form of folate.
- Body-ready folate.
- Requires no extra steps by the body to be absorbed and enter circulation.

We certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Sincerely,

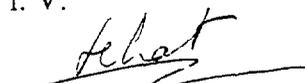
Merck KGaA

ppa.



Dr. Roland Martin

i. V.



Dr. Najib Sehat

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Germany

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